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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,596	08/27/2003 <sup>1</sup>	John W. Elling	99,097-A	4972

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EXAMINER

ZEMAN, MARY K

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/649,596	<b>Applicant(s)</b> ELLING ET AL.	
	<b>Examiner</b> Mary K Zeman	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 69-90 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

Claims 69-90 are pending in this application.

Claims 1-68 were canceled by preliminary amendment filed 3/25/04.

### ***Drawings***

The drawings as filed are acceptable to the examiner.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 17, line 26.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 69-80 and 83-87 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to methods of manipulating data, that do not result in a concrete, tangible and useful result as required. For example, in claim 69, the final output is a "molecular feature set" that must be further manipulated, transformed or worked on to be used. See MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT &T*, 172 F.3d at 1358, 50 USPQ2d at

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1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 69, 72-82, 84, 88, 89 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Cramer (USP 5,307,287 of record in the parent application).

Cramer et al. (USP 5,307,287) disclose methods of defining molecular feature sets which correlate with a biological activity. Cramer discloses the Comparative molecular field analysis (CoMFA) which is a computer implemented QSAR program which identifies shapes and features of molecules that are likely to have a given activity. Cramer notes that the 3D-QSAR techniques are based upon the idea that it is possible to derive shape descriptors which when applied to substrates will reflect the different levels of the biological activity (column 3 lines 48-51). These are “molecular feature sets” that are “likely to be responsible for a given activity...” as described in the instant claim 69. The invention of Cramer et al. use descriptors of the shape of the molecule derived from steric and electrostatic interactions, interaction energies and measured activities of known compounds in a 3-dimensional lattice data structure. The known molecules having the activity are used to generate equivalents to the “molecular substructure keys” of the claims. The molecules to be compared to the keys are grouped based upon their CoMFA interaction energies- which do not take into account the activity, per se. (columns 9-11) Then the groups or lattices are probed for common features and activities (columns 11-15), which can be output in a variety of ways (columns 15-17). Cramer et al. discuss the predictive power of the method to identify molecular structures which underlie the activity, and generate new structures for testing (columns 17-19). Cramer sets forth computer programs, programmed

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computers, systems, media etc. (columns 19-22 and appendix) As such, Cramer et al. meets the limitations of the rejected claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 70, 71, 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramer et al. as applied to claims 69, 72-82, 84, 88, 89 and 90 above, in view of van Osdol (1994- PTO-1449).

The above rejected claims add the limitation that clustering of groups is performed by self organizing maps.

As set forth above, Cramer et al. (USP 5,307,287 of record in the parent application) disclose methods of defining molecular feature sets which correlate with a biological activity. Cramer discloses the Comparative molecular field analysis (CoMFA) which is a computer implemented QSAR program which identifies shapes and features of molecules that are likely to have a given activity. Cramer notes that the 3D-QSAR techniques are based upon the idea that it is possible to derive shape descriptors which when applied to substrates will reflect the different levels of the biological activity (column 3 lines 48-51). These are "molecular feature sets" that are "likely to be responsible for a given activity..." as described in the instant claim 69. The invention of Cramer et al. use descriptors of the shape of the molecule derived from steric and electrostatic interactions, interaction energies and measured activities of known compounds in a 3-dimensional lattice data structure. The known molecules having the activity are used to generate equivalents to the "molecular substructure keys" of the claims. The molecules to be compared to the keys are grouped based upon their CoMFA interaction energies- which do not take into account the activity, per se. (columns 9-11) Then the groups or lattices are probed for common features and activities (columns 11-15), which can be output in a variety of ways

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(columns 15-17). Cramer et al. discuss the predictive power of the method to identify molecular structures which underlie the activity, and generate new structures for testing (columns 17-19). Cramer sets forth computer programs, programmed computers, systems, media etc. (columns 19-22 and appendix)

Cramer et al. do not teach clustering of identified features or groups using self-organizing maps.

Van Osdol et al. (Journal of the National Cancer Institute vol. 86, no. 24, pages 1853-1859, 1994 of record in parent application) disclose the usefulness of the self organizing map in the grouping of molecules based upon their topology and activity. The SOM captures topologic features (analogous to shape descriptors of Cramer and molecular feature sets of the instant claims) and represents those features in two dimensions. These methods allow for the clustering of similar chemical structures which have similar levels of biological activity. After training, the grouping is done in an unsupervised manner, which is superior to the supervised grouping of Cramer et al.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have utilized the self organizing map technology of van Osdol in the methods of Cramer et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use the grouping functions of the self organizing map algorithms of van Osdol, as once the system/ network is trained, the grouping and clustering can proceed unsupervised, which is clearly an advance over the supervised grouping of Cramer et al. Unsupervised grouping and organizing requires little or no human intervention, allowing for greater automation of the methods of Cramer et al. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. The self organizing map algorithms of van Osdol appear completely compatible with those of Cramer et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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***Conclusion***


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the contents of the electronic file wrapper, or on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~~MARY K. ZEMAN~~  
~~PRIMARY EXAMINER~~

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
10/16/03 4/21/04